

Serial No. 10/809,140  
Chaouk et al.  
Response to Office Action

### REMARKS

#### Restriction Requirement

Applicants still do not believe that the restriction requirement is correctly applied. However, claims 9-12 have been cancelled to expedite prosecution.

#### Claim Rejection

The rejection of claims 1-8 under §103(a) as obvious over US 6,152,943 to Sawhney ("Sawhney") in view of U.S. Patent No. 5,443,454 to Tanabe ("Tanabe") is repeated and is again traversed.

The Examiner and Applicants are in disagreement over what Sawhney teaches, whether one skilled in the art would combine Sawhney and Tanabe and whether, if one skilled in the art did combine Sawhney and Tanabe the claimed invention would result.

#### Sawhney teaches in situ formation of the hydrogel

Sawhney teaches a method and device for forming a hydrogel in situ- in a body cavity or void. Sawhney teaches away from premature formation of the hydrogel, meaning formation of the hydrogel before it is at the body cavity or void. This point of the invention is stated very clearly several times. See the abstract "deliver two or more fluent prepolymer solutions without premature crosslinking" and col. 1, lines 8-10 "delivering two or more liquid components to form a hydrogel implant in situ".

The paragraph beginning at col. 3, line 7 reads:

In accordance with the present invention, delivery systems are provided for delivering separate prepolymer components of a hydrogel system, without premature crosslinking within the delivery system. In one embodiment, the delivery system includes an occlusive element for anchoring a distal end and isolating the region in which the hydrogel is to be formed in situ. In another embodiment, the delivery system may include variable stiffness regions to enable passage through tortuous anatomy. In yet another embodiment, the delivery system includes a steerable tip. In still further alternative embodiments, the prepolymer components of the hydrogel system may be mixed together in a mixing chamber disposed in a distal region of the delivery system, and then extruded into the body lumen or void during the crosslinking process, to reduce washout or dilution of the components. (emphasis added)

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The embodiment illustrated by Figure 3, which has been discussed in the prior Response as well as in the latest Office Action is one embodiment of the delivery systems- all of which are used to deliver a hydrogel system without premature crosslinking.

The embodiment of Figure 3 is discussed further at col. 10, lines 1-25 (this is also quoted in the Office Action):

Delivery system 40 is particularly suitable for use where the polymeric material is to be applied to a surface of a natural or induced body lumen or void, and through which a body fluid is not flowing at very high velocity. Prepolymer solutions are injected via lumens 49 and 49' into mixing chamber at a rate selected so that the prepolymer solutions begin crosslinking in chamber 46, with the resulting partially-formed gel being extruded through outlet ports 47 into the lumen or void. In this manner, washout or dilution of the prepolymer solutions during deposition is reduced or eliminated, thereby reducing the risk that the prepolymer solutions will cause embolization in other portions of, for example, the vascular system.

Delivery system 40 therefore prevents premature crosslinking of the prepolymer solutions, while also enabling the solutions to be mixed and partially gelled before being deposited in the body lumen or void. Delivery system may be especially useful in depositing hydrogel systems that form both physical and chemical crosslinks, wherein the physical crosslinking is accomplished by mixing the prepolymer solutions in mixing chamber 46. The partial gel extruded from mixing chamber 46 through outlet ports 47 then may have sufficient mechanical integrity to remain in position in the body lumen or void during the chemical crosslinking process.

The Office Action argues that the "partially formed" gel extruded from the mixing chamber would "obviously or inherently existed with some string-like characteristics." This is an unsupported statement. There is no statement in Sawhney to support this statement. In fact the opposite is true- all statements in Sawhney teach away from this statement. Perhaps the primary definition for "extrude" found in the online edition of Merriam-Webster's dictionary <http://www.m-w.com/dictionary/extrude> should be used: "1 : to force, press, or push out". A glob of partially formed gel can be "extruded" from a catheter, and this is more likely what is taught by Sawhney. A glob of partially formed gel pushed from a catheter could have a number of "shapes" or no shape at all. The Examiner's statement that it would "obviously" have "string-like characteristics" is baseless.

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No showing that one skilled in the art would combine Sawhney and Tanabe

The Office Action argues that there is motivation to combine the teachings of Sawhney and Tanabe. The Applicants have pointed out how Sawhney teaches away from the claimed invention. Sawhney teaches away from forming the hydrogel within the catheter and extruding it from the catheter as a string. Sawhney explicitly teaches avoiding premature crosslinking of the hydrogel.

The Examiner argues that this aspect of the claimed invention is taught by Tanabe and that one of ordinary skill in the art would have combined the method of Tanabe with that of Sawhney in order to eliminate the dispersing and leakage of an embolic agent out of the site.

Sawhney already has recognized and provided a solution to the problem of dispersion-delivering a partially polymerized product. One of skill in the art in reading Sawhney would not be motivated to provide a solid composition as taught by Tanabe since Sawhney already teaches a solution. Furthermore, Sawhney specifically teaches to not deliver a solid hydrogel.

The Examiner is improperly engaged in hindsight to modify Sawhney to reproduce the invention that is claimed. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein only that which the inventor taught is used against its teacher").

Since the cited references do not anticipate or render obvious the claims, the issuance of a notice of allowance is respectfully requested.

Respectfully submitted,

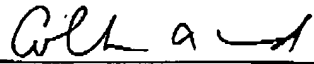


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